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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/639,859	08/16/2000	Leonard S. Girsh	5163*3	2441

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/639,859	GIRSH, LEONARD S.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-54,59,60,65-77 and 97-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-54,59,60,65-77 and 97-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20041004*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed October 21, 2004 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 45-54, 59, 60, 65-77 and 97-106 are pending.

Applicants' amendment and the Declaration of Dr. Leonard Girsh filed October 21, 2004 are acknowledged, and applicants' response has been fully considered. Claims 45, 50, 51, 59, 60, 75 and 97-100 have been amended, 55-58, 61-64 and 96 have been cancelled, and new claims 101-106 have been added. Thus, claims 45-54, 59, 60, 65-77 and 97-106 are examined.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 45-77 and 96-100 under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' cancellation of the claim, applicant's amendment to the claim, applicant's response at pages 11-16 in the amendment and Declaration by Dr. Leonard Girsh filed October 21, 2004.

4. The previous rejection of claims 55-58, 61-64, 96-98 and 100 under 35 U.S.C.112, second paragraph, regarding the term "said aliphatic side chain is a short chain fatty acid", "L-gamma amino butyric acid" or "or and", is withdrawn in view of applicants' cancellation of the claim, and applicants' amendment of the claim, and applicant's response at pages 10-11 in the amendment filed October 21, 2004.

Claim Objection

5. Claim 53 is objected to because of the use of misspelled word "protoglycan". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 59-60, 72, 75, 99-101 and 103 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. The claims are directed to an anabolic medicament comprising at least one mucopolysaccharide extracellular matrix compound, at least one polar surface active lipid, and a plurality of amino acids being present at a molar ratio which is characteristic of cyclosporin (claim 101), wherein no more than 10% of the amino acids are in D-form, and the molar ratio comprises 2 moles L-valine: 4 moles L-leucine: 2-moles L-alanine, or characteristic of fibrinogen (the molar ratio of amino acids recited in claim 102). While the specification indicates that the molar ratio of amino acids of cyclosporin (page 14), and the molar ratio of amino acids of fibrinogen (the paragraph bridged pages 12-13), the prior art does not indicate the same molar ratio of amino acids for cyclosporin (Durette, U. S. Patent 5,236,899, see column 2) and fibrinogen (Henschen *et al.*, Ann N. Y. Acad. Sci. 408, 28-43 (1983), see Table 1), e.g., Durette teaches cyclosporin A has an amino acid composition of 1 mole of L-Ala; 1 mole of D-Ala; 4 moles of N-methyl-L-Leu; 1 mole of N-methyl-L-Val; 1 mole of L-Val; 1 mole of N-methyl-Gly; 1 mole of α-aminobutyric acid (Abu); and 1 mole of (4R)-4[(E)-2-butenyl]-4-methyl-L-Thr, there is no methionine, gamma-aminobutyric acid, and betaine in the composition; and Henschen *et al.* disclose the amino acid composition of fibrinogen (Table 1), which is different from the amino acid ratios indicated in

the claimed invention. For these reasons, the claimed invention is inoperative and therefore lacks utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 59-60, 72, 75, 99-101 and 103 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as indicated in the paragraph 6.

8. Claims 45-54, 65-71, 73-74, 76, 77, 97, 98 and 104-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 45-54, 65-71, 73-74, 76, 77, 97, 98 and 104-106 are directed to an anabolic medicament for treating a damaged tissue comprising at least one mucopolysaccharide extracellular matrix compound, at least one polar surface active lipid, and a plurality of amino acids being present at a molar ratio which is characteristic of human breast tissue protein, wherein no more than 10% of the amino acids are in D-form. While the specification indicates a therapeutic composition comprises a composition and uses thereof comprising a mixture of one or more L-amino acids at the molar ratio corresponds to the molar ratio of amino acid

components in a mammalian tissue protein (e.g., healthy skin protein or fibrinogen) or in a medicament (cylosporin or penicillin; pages 8, 11-14), the specification does not disclose a genus of variants for human breast tissue proteins contained in the anabolic medicament.

The specification indicates a preferred source of amino acids is Neocate elemental diet which contains essential and non-essential amino acids, dried glucose syrup, fat, minerals, trace elements and vitamins (page 17, lines 11-16), and Neocate elemental diet is included in some of the formulation for treating disease (e.g., cases 1 and 7) . However, the specification does not describe a genus of variants for human breast tissue proteins contained in the anabolic medicament. A description of a specific nutritional supplement Neocate based on the amino acid composition of human breast milk protein in the prior art does not provide original descriptive support for a genus of variants for human breast tissue proteins contained in the anabolic medicament. The disclosure of a nutritional supplement Neocate contained in the medicament does not meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Applicants have described nutritional supplement Neocate is contained in the medicament, however, a genus of variants for human breast tissue proteins contained in the anabolic medicament have not been described nor disclosed.

The skilled artisan cannot envision all the contemplated human breast tissue proteins based upon the suggestion of a known nutritional supplement from the prior art. The detailed amino acid compositions for various human breast tissue proteins must be taught, therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of preparation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF'S were found unpatentable due to lack of written description for the broad class.

Therefore, only those embodiments described and disclosed meet the written description requirement and not the full breadth of the claim meets the written description provision of 35 USC 1 12, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

In response, applicants indicate claim 45 has been amended to recite the ratio of the plurality of L-amino acids in the claimed medicament is characteristic of human breast milk proteins, and the amino acid ratio of breast milk proteins is known in the art, e.g., infant nutritional supplement Neocate containing proportions of L-amino acids based on human breast

milk (pages 11-12 of the response; Bines et al., J. Pediatr. Gastroenterol. and Nutr. 26 (2), 123-128 (1998), Exhibit A; Table 2 Exhibit B).

Declaration submitted by Dr. Leonard Girsh, which shows the actual treatment of a 71-year-old female patient suffering from Crohn's disease (Exh. D). The Applicant administered to this patient a medicament comprising about 10.6 g Neocate infant formula containing L-amino acids and glycine, in the genetic code and molar ratio of breast milk protein from human breast tissue; about 50-100 mg lecithin; about 12.5-40 mg phosphatidyl choline; about 225 mg EPA from fish oil; 500 mg flaxseed oil (equivalent of about 275-325 mg linolenic acid); and extracellular matrix components comprising collagen, proteoglycan aggregate complex of cartilage and chondroitin sulfate (shark cartilage 740 mg per capsule, twice daily; paragraph 6); the comparison of the medicament for the treatment with the medicament cited in claim 45 (paragraph 7); treatment with this composition caused a significant improvement in the Crohn's disease patient, and the patient was able to take a much-reduced dose of anti-inflammatory corticosteroids (paragraph 8).

Applicant's response and Declaration by Dr. Leonard Girsh have been considered, however, the argument is not persuasive because the amended claim 45 does not indicate the molar ratio of a specific human breast tissue protein such as human breast milk protein, and there are many proteins in the human breast tissue. In the argument applicants indicate the human breast tissue protein refers to human breast milk protein, however, this limitation is not cited in the claim. As indicated in the section above, the specification does not describe a genus of variants for human breast tissue proteins contained in the anabolic medicament, thus the full

breadth of the claim does not meet the written description provision of 35 USC 1 12, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 45-54, 65-71, 73-74, 76, 77, 97, 98, 102 and 104-106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 45-54, 65-71, 73-74, 76, 77, 97, 98 and 104-106 are indefinite because of the use of the term "human breast tissue protein". The cited term renders the claim indefinite, it is unclear which protein the human breast tissue protein refers to, and what is the characteristic amino acid molar ratio for the human breast tissue protein since there are many human breast tissue proteins, e.g., lactoferrin (Teng et al., WO 92/21752). Claims 46-54, 65-71, 73-74, 76, 77, 97, 98 and 104-106 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate claim 45 has been amended to recite the ratio of the plurality of L-amino acids in the claimed medicament is characteristic of human breast milk protein, and the amino acid ratio of breast milk protein is known in the art. Claim 45 now identifies both the tissue and protein in the tissue from which the claimed amino acid ratio is derived, and one skilled in the art would be aware of the claimed amino acid ratio (page 10 of the response). The response has been considered, however, the argument is not persuasive because the amended claim 45 does not indicate the molar ratio of a specific human breast tissue protein

and there are many proteins in the human breast tissue. In the argument applicants indicate the human breast tissue protein in the claim refers to human breast milk protein, however, this limitation is not cited in the claim.

11. Claim 73 is indefinite because claim 73 has the same scope as claim 71.

12. Claim 102 is indefinite as to which species the skin refers to, e.g., is it human, an animal or fish?

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK
January 03, 2005